REMARKS

The Applicants wish to thank the Examiner for reviewing the present application.

Claim Amendments

Claims 1 and 3 have been amended to further clarify over the cited references and to recite further structure in defining the hinge points. No new subject matter is believed to be added by way of these amendments.

Claim Rejections – 35 U.S.C. § 102(e)

The Examiner has rejected claim 1 under 35 U.S.C. § 102(e) as being anticipated by Israel et al. (U.S. 5,733,303). It is the Examiner's position that Figure 2 in Israel shows each linkage having a pair of hinge points, namely the corners of the links, which are capable of deforming upon radial expansion. It is also the Examiner's position that there is no structure recited in claim 1 other than hinge points, and thus Israel discloses the hinges allow for bending, which thus have "zones of relative weakness" along the links since all materials have the capability of being deformed.

Claim 1 has been amended to provide further clarity over Israel and to recite additional structure defining the hinge points. The Applicants respectfully disagree with the Examiner's rejection of claim 1 and traverse the rejection for at least the reasons discussed below.

Claim 1 recites the linkages of the stent "having a pair of hinge points each defining an axis of rotation between adjacent pairs of said linkages,....wherein said hinge points are provided by deformable zones of relative weakness at *predefined locations* along said links *to control the locations* within said linkage at which bending will occur" (emphasis added).

Israel simply does not teach any hinge points. A hinge point has certain defined characteristics that provide the preferential location for relative rotation of interconnected structures. Typically, hinges are formed from two parts mechanically connected by a pin, but it is also common to use so called "living" hinges in which a preferential axis of rotation is defined by the material characteristics in a particular zone. Thus, the recitation in claim 1 of the provision of hinge points implies the presence of a specific structure that defines a preferred axis of rotation to pivotally connect a pair of adjacent structures. In other words, the hinges "control the locations within said linkage at which bending will occur," as recited in claim 1. There is no such

teaching or structure present in Israel. Making the linkage of the present application of uniform width and uniform material as shown in Israel does not provide hinge points, i.e., a structure that defines an axis of rotation. The stent then would not have the desirable characteristics attributed to the present invention, nor would it meet the requirements of claim 1.

The Examiner has cited col. 3 lines 38-40, 43-45, and 48-49 to support his position that Israel discloses hinge points. However, the bending described in these passages cannot result from hinge points "provided by deformable zones of relative weakness at predefined locations along said links to control the locations within said linkage at which bending will occur," as in Israel there is no predefined zone controlling the location or the direction at which bending will occur. On the contrary, col. 3 lines 48-49 of Israel states that the stent "can bend in any direction and in more than one direction at any time."

The Applicants note that just because Israel shows adjacent links connected by a corner it does not teach or imply that these corners predefine a hinge point thereby controlling where hinging will occur during expansion. Such an assumption would ignore the practicalities of the manufacturer of the stents that would be apparent to a person skilled in the art.

The manufacturing techniques of stents require the cutting of the linkage by laser from a stainless steel tube and the subsequent polishing of the resultant stent. The stents are made from a biocompatible material such as a stainless steel which has a certain granular structure. Typically, the stent links are in the order of ten grains across and cutting and polishing operations tends to occur at granular level causing the wholesale loss of a grain rather than the severance of a grain. The loss of a grain in the width of a link can cause a significant loss in the cross section of that link and occurs in an entirely and unpredictable manner. With the link in the order of ten grains across, the loss of one grain would result in a 10% reduction in the cross section and a correspondingly significant change in the properties of the link. As such, in practical terms, the skilled technician would recognize that the performance of the linkage in Israel cannot be predicted from stent to stent. Israel is clearly intended to provide a substantially uniform width, but ignores the reality that in attempting to do so it will inevitably cause unpredictable but significant variations in that width that will effect its performance and expansion.

Again therefore, in the absence of any clear teachings of a specific zone that is provided for hinging purposes, the person skilled in the art would understand that the linkage shown in Isreal will expand in an unpredictable manner from stent to stent. By contrast, the teachings of the present application require the provision of hinge points that define the zones at which

bending can occur in a controlled manner. In the examples provided in the specification, the change in dimension of the link is in the order of 50% such that variations incurred due to polishing operations will not impact the preferential bending action that occurs at the hinge point.

The functionality of the stent and the provision of the hinge points of the present application is illustrated in the accompanying Exhibit A. This is a finite element analysis of the strain to which the linkage of the stent is subjected upon radial expansion. The dark blue portions of the analysis indicate zero strain and the highest strain areas are indicated in red. The similarity between the linkage shown in Exhibit A and that illustrated in Figure 13 of the application is self evident. It will be noted that the structure corresponding to the axial links 20 are substantially free of strain after expansion with small amounts of strain located at a pair of spaced locations along the link adjacent the enlarged nodes. The link 20 thus remains substantially linear after its expansion. The circumferential links 18 and 38 are subjected to higher degrees of strain to permit rotation of the links 20 relative to the struts 14.

Exhibit B is a finite element analysis showing the stress distribution in the expanded linkage. Again it can be seen that the higher levels of stress occur at spaced locations on the links 20, 18 and 28 in defined zones.

The distribution of the strain resulting from expansion, and the relatively strain free disposition of the links 18 have important consequences in the practical installation of the stent. As will be appreciated by the Examiner, the stent is expanded by the inflation of a balloon within the stent. Once expanded, the balloon is removed leaving the stent in place. Because of the mechanical linkage utilized in most stents, as well as the absence of hinge points disclosed in the present application, there is a tendency for the linkage to recoil or attempt to revert to its original configuration upon removal of the inflation balloon, even where plastic deformation has occurred. This is a simple mechanical reality as a result of the yield curve of most materials. This recoil is a significant problem in that any reduction of the diameter of the stent reduces the cross section of the blood vessel and ultimately an insecure fastening of the stent within the vessel. It is not practical to over expand the stent within the vessel to compensate as this would lead to damage of the walls of the vessel which is undesirable. Each strained link in the linkage contributes to the recoil so that the effect is cumulative.

The linkage of the present application mitigates this effect by defining the hinge points that are subject to strain and minimizing the strain that is applied to the major lengths of the axial links. Thus, the circumferential links are subject to high levels of strain leading to a plastic

deformation whereas the linear portions of axial links are largely free of strain and therefore contribute no recoil. As such, the recoil is limited to the recoil of the circumferential links and the specific hinge points that have been deformed and a stable expanded form is obtained.

By contrast, the uniform width links shown in Israel would be subject to a uniform strain distribution over the length of the links. It should be noted that the loading applied to the stent is not a point loading at opposite ends of the link but rather is a radial load applied over the whole linkage by virtue of its contact with the balloon catheter. Accordingly, with a uniform size of link, it can be expected that the strain will be also uniformly distributed. This means that in the absence of the defined hinge points, the various links are each subjected a degree of strain and each contribute to the recoil upon removal of the inflation pressure. The degree of recoil is therefore significant leading either to vessel damage if it is over expanded or reduced flow capacity if it is under expanded.

It can be seen therefore particularly from Exhibit A that the provision of the deformable zone allows the strain to occur in specific regions whilst leaving the links relatively strain free and resulting in a predictable controlled expansion of the stent.

The absence of hinge points from the configuration of link shown in Israel is also anticipated to present further practical problems. The loading of the uniform width links shown in Israel is most likely to cause the bights of the link to move out of the plane of the links as they are expanded. In effect, this causes the bights to project radially from the body of the stent and into the vessel wall. Whilst a finite element analysis has not been performed on the configuration of stent shown in Israel, intuitively the radial expansion of the links of Isreal would result in a radial projection of the bights.

Claim Rejections – 35 U.S.C. § 103

Claim 2:

The Examiner has rejected claim 2 as unpatentable over Israel in view of Orth et al. (U.S. 5,591,197). It is the Examiner's position that Israel discloses all elements of claim 2 except for the zones of relative weakness being provided by a reduced cross-sectional area, which the Examiner states is disclosed by Orth in Figures 3A and 4A, as well as col. 6, lines 51-54. It is the Examiner's position that it would have been obvious to a person skilled in the art to combine the zones of reduced cross-sectional area in Orth with the teachings of Israel.

The Applicants respectfully disagree with the Examiner. As previously submitted, it is the

Applicants' position that although the structure shown in Orth may teach a hinge point in a connecting member that connects to stents, there is nothing within Orth itself to suggest that it could be used in other areas of the stent. Similarly, there is nothing in Israel to suggest that it requires a mechanism to provide controlled bending that would enable the teachings of Orth to be applied in the manner suggested by the Examiner. As such, the combination of Israel and Orth to arrive at the invention claimed is not a matter of ordinary skill in the art given the lack of teaching in the principal reference of Israel of the need for the structure shown as being used in an entirely different manner in Orth.

The Examiner has rejected this argument, adopting the position that the KSR decision explains why no teaching is required to support a finding of obviousness, and that combining Israel and Orth is simply the combination of known features that merely produce predictable results when combined.

The Applicants believe that the Examiner has failed to consider that a person skilled in the art and faced with Israel and Orth would not even be enlightened as to the need of providing areas of weakness to allow for controlled and predictable expansion, which is a distinguishing and inventive feature of the Applicants' invention. A person skilled in the art would not be led to this Eureka moment by consulting Israel or Orth because neither suggests the need of a structure to provide controlled radial expansion. As discussed in reference to claim 1, Israel simply does not provide or contemplate the need for predefined areas of weakness to control and predict the expansion as radial pressure is applied. Additionally, the notches in Orth are not used to provide controlled expansion. The purpose of the notched connecting members in Orth are to buckle under pressure and project a barb into a blood vessel wall (e.g. Orth, col. 4 lines 3-7). This is a function independent of and unrelated to ensuring the expansion of the stent is controlled, predictable, and uniform. Therefore, a person skilled in the art would not be led to combine Israel and Orth as neither teaches nor suggests the need for predefined areas of weakness.

Additionally, the Applicants believe that Israel teaches away from Orth. In the background section of Israel (col. 1 lines 42-44), Israel criticizes prior art stents that provide a twisting motion that is harmful to the blood vessel in which the stent is inserted. However, during the expansion of the stent in Orth, the connecting member buckles and forms a projecting barb for penetrating into the blood vessel wall. Israel teaches that motion such as this may be harmful to the blood vessel. Therefore, a skilled person with the teachings of Israel would be led away from consulting the apparatus described by Orth.

For at least the above reasons, the Applicants believe that claim 2 is patentable over Israel in view of Orth.

Claim 3:

The Examiner has rejected claim 3 as unpatentable over Israel in view of Hickle (U.S. 5,139,480). It is the Examiner's position that Israel teaches all elements of claim 3 except for the linkages having intersections of the axial and circumferential links forming nodes with greater cross-sections than the central portion of the adjacent link, and that Hickle provides this missing teaching. The Examiner is of the position that a person skilled in the art would incorporate the reduced cross-section linkages of Hickle into the stent of Isreal and yield a stent as claimed in claim 3.

The Applicants respectfully disagree. From the Examiner's description of Hickle, it is assumed that the Examiner is referring to the "adjacent links" as being portions of strip 32 ('necked' from strip 22 in Figure 3) wherein adjacent portions of strip 32 are connected by tab 36 of greater cross-section. Such a structure only exists after expansion of the stent is complete. It is clear from observing the unexpanded stent (e.g. Figure 2) that there are no adjacent links intersecting to form a node having a cross-section greater than the central portion of the adjacent links. This further implies that Hickle does not define spaced hinge points. The combination strip portion 32 and node 36 cannot define a hinge as there would be no hinging action after the stent has expanded. The purpose of the hinge is to facilitate predicted and controlled expansion of the stent. Figures 2, 3, 5, and 7 (in which the stent is shown in an unexpanded position) clearly show there is no such spaced hinge points defined. As discussed in relation to claim 1, Israel also does not teach or suggest spaced hinge points. Therefore, for at least these reasons, the Applicants believe that claim 3 is neither anticipated nor suggested by the combined teachings of Israel and Hickle.

Claims 4-17:

The Examiner has rejected claim 4 as unpatentable over Israel in view of Hickle and in further view of U.S. 4,994,071 to MacGregor.

Claim 4 incorporates all of the subject matter recited in claim 3. As discussed above, the Applicants believe that the combined teachings of Israel and Hickle do not teach or suggest claim 3. The Applicants further believe that MacGregor does not supply the missing teaching of spaced hinge points. Accordingly, the Applicants believe that claim 4, and also claims 5 to 17

are novel and non-obvious over the cited references.

Summary

In view of the foregoing, the Applicants believe claims 1 to 17 are in condition for allowance. The Applicants request reconsideration and withdrawal of the rejections and objections and early allowance of the present application.

Respectfully submitted,

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Exhibit A

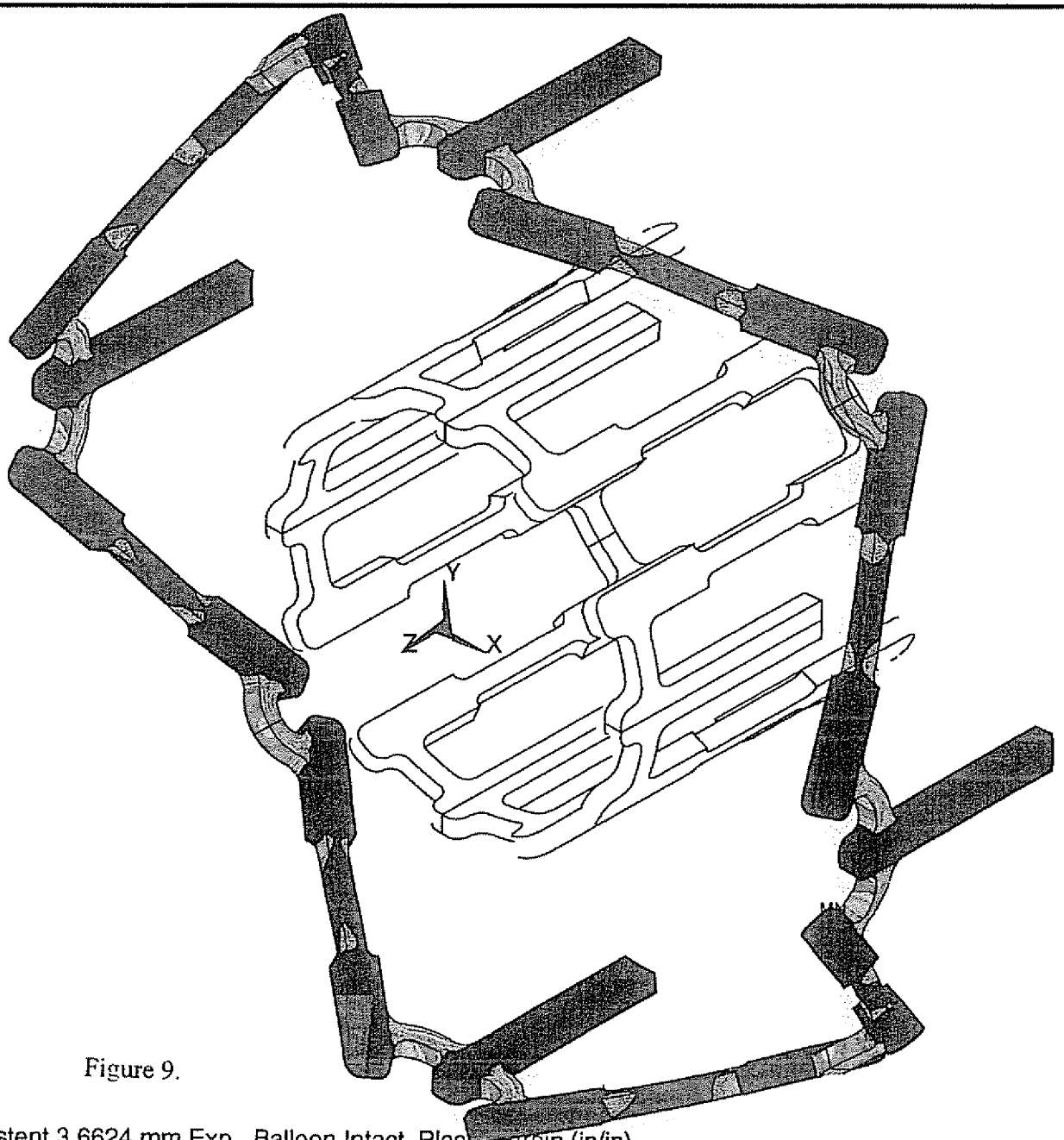

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Figure 9.

Medstent 3.6624 mm Exp., Balloon Intact, Plastic Strain (in/in)

Exhibit B

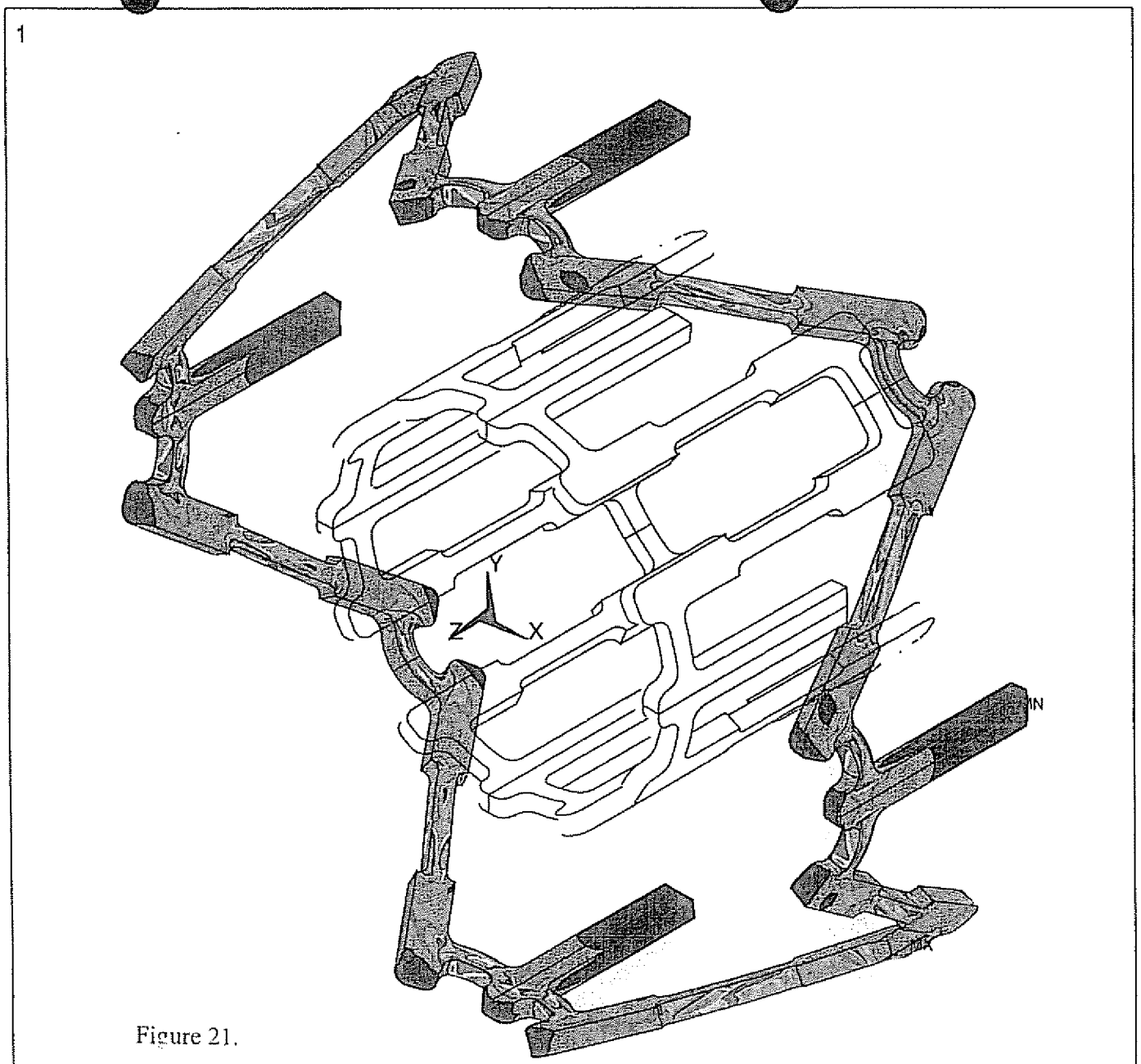

Figure 21.

Medstent 3.6624 mm Exp., 100mmHg, Von Mises Stress (psi)